



General

Guideline Title

Topical fluoride for caries prevention.

Bibliographic Source(s)

Weyant RJ, Tracy SL, Anselmo T, Beltr n-Aguilar ED, Donly KJ, Frese WA, Hujoel PP, Iafolla TJ, Kohn W, Kumar J, Levy SM, Tinanoff N, Wright JT, Zero D, Aravamudhan K, Frantsve-Hawley J, Meyer DM. Topical fluoride for caries prevention. Chicago (IL): American Dental Association; 2013 Nov. 118 p. [118 references]

Guideline Status

This is the current release of the guideline.

This guideline updates a previously released version: American Dental Association Council on Scientific Affairs. Professionally applied topical fluoride: evidence-based clinical recommendations. J Am Dent Assoc. 2006 Aug;137(8):1151-9. [45 references]

This guideline meets NGC's 2013 (revised) inclusion criteria.

Recommendations

Major Recommendations

The levels of certainty (high-low) and the grade of recommendations (strong-against) are defined at the end of the "Major Recommendations" field.

Clinical Recommendations

For individuals at elevated risk of developing dental caries, the panel made clinical recommendations for the use of specific topical fluoride agents (as shown in the table below); these recommendations are based on the evidence statements and the balance of benefits with potential harm. The panel recommends topical fluoride agents only for people at elevated risk for dental caries. Further details of the strength of the clinical recommendations for each form of topical fluoride and age group are available in Appendix 1 of the original guideline document.

The panel recommends the following for people at risk of developing dental caries: 2.26% fluoride varnish or 1.23% fluoride (acidulated phosphate fluoride [APF]) gel, or a prescription-strength, home-use 0.5% fluoride gel or paste or 0.09% fluoride mouthrinse for patients 6 years or older. Only 2.26% fluoride varnish is recommended for children younger than 6 years. The strengths of the recommendations for the recommended products varied from "in favor" to "expert opinion for".

The panel judged that the benefits outweighed the potential for harm for all professionally applied and prescription-strength, home-use topical fluoride agents and age groups except for children younger than 6 years. In these children, the risk of experiencing adverse events (particularly

nausea and vomiting) associated with swallowing professionally applied topical fluoride agents outweighed the potential benefits of using all of the topical fluoride agents except for 2.26 percent fluoride varnish.

Clinical Recommendations for Use of Professionally-Applied or Prescription-Strength, Home-Use Topical Fluoride Agents for Caries Prevention in Patients at Elevated Risk of Developing Caries

| Age Group or Dentition Affected | Professionally-Applied Topical Fluoride Agent | Prescription-Strength, Home-Use Topical Fluoride Agent |
|---------------------------------|--|---|
| Younger than 6 Years | 2.26% fluoride varnish at least every 3 to 6 months (In Favor) | |
| 6-18 Years | 2.26% fluoride varnish at least every 3 to 6 months (In Favor) OR 1.23% fluoride (acidulated phosphate fluoride [APF]) gel for 4 minutes at least every 3 to 6 months (In Favor) | 0.09% fluoride mouthrinse at least weekly (In Favor) OR 0.5% fluoride gel or paste twice daily (Expert Opinion For) |
| Older than 18 Years | 2.26% fluoride varnish at least every 3 to 6 months (Expert Opinion For) OR 1.23% fluoride (APF) gel for at least 4 minutes every 3 to 6 months (Expert Opinion For) | 0.09% fluoride mouthrinse at least weekly (Expert Opinion For) OR 0.5% fluoride gel or paste twice daily (Expert Opinion For) |
| Adult Root Caries | 2.26% fluoride varnish at least every 3 to 6 months (Expert Opinion For) OR 1.23% fluoride (APF) gel for 4 minutes at least every 3 to 6 months (Expert Opinion For) | 0.09% fluoride mouthrinse daily (Expert Opinion For) OR 0.5% fluoride gel or paste twice daily (Expert Opinion For) |

Additional Information:

- 0.1% fluoride varnish, 1.23% fluoride (APF) foam, or prophylaxis pastes are not recommended for preventing coronal caries in all age groups (Expert Opinion Against or Against). See American Dental Association (ADA) publication for recommendation strength by age group. The full report, which includes more details, is available at ebd.ada.org [redacted].
- No prescription-strength or professionally-applied topical fluoride agents except 2.26% fluoride varnish are recommended for children younger than 6 years (Expert Opinion Against or Against), but practitioners may consider the use of these other agents on the basis of their assessment of individual patient factors that alter the benefit to harm relationship.
- Prophylaxis before 1.23% fluoride (APF) gel application is not necessary for coronal caries prevention in all age groups (Expert Opinion Against or Against). See ADA publication for recommendation strength by age group. No recommendation can be made for prophylaxis prior to application of other topical fluoride agents. The full report, which includes more details, is available at the ebd.ada.org [redacted].

Patients at low risk of developing caries may not need additional topical fluorides other than over-the-counter fluoridated toothpaste and fluoridated water.

Definitions:

Level of Certainty Categories for Summary Effect Estimates*

| Level of Certainty in Effect Estimate | Description |
|---------------------------------------|---|
| High | <p>The body of evidence usually includes consistent results from well-designed, well-conducted studies in representative populations. This conclusion is unlikely to be strongly affected by the results of future studies.</p> <p>This statement is strongly established by the best available evidence.</p> |
| Moderate | <p>As more information becomes available, the magnitude or direction of the observed effect could change, and this change could be large enough to alter the conclusion.</p> <p>This statement is based on preliminary determination from the current best available evidence, but confidence in the estimate is constrained by one or more factors, such as:</p> <ul style="list-style-type: none"> • The number, size, or risk of bias of individual studies • Inconsistency** of findings across individual studies • Limited applicability due to the populations of interest • Lack of coherence in the chain of evidence |
| Low | <p>More information could allow a reliable estimation of effects on health outcomes.</p> <p>The available evidence is insufficient to support the statement or the statement is based on extrapolation from the best available evidence. Evidence is insufficient or the reliability of estimated effects is limited by factors such as:</p> <ul style="list-style-type: none"> • The limited number or size of studies • Important flaws in study design or methods leading to high risk of bias • Inconsistency** of findings across individual studies • Gaps in the chain of evidence • Findings not applicable to the populations of interest • A lack of information on important health outcomes |

*Adapted from the United States Preventive Services Task Force (USPSTF) system

**Inconsistency of findings is a concept incorporating direction of effect, similarity of point estimates, overlapping of confidence intervals, and statistical heterogeneity. Statistical heterogeneity (I^2) is interpreted as: $I^2 < 50\%$ is low; $50 < I^2 < 75\%$ is moderate; $I^2 > 75\%$ is high. Direction of effect and overlapping confidence intervals are also taken into account.

Definitions for the Strength of Recommendations*

| Grade | Strength of Recommendation |
|--------------------------|--|
| Strong | Evidence strongly supports providing this intervention |
| In Favor | Evidence favors providing this intervention |
| Weak | Evidence suggests implementing this intervention after alternatives have been considered |
| Expert Opinion For** | Evidence is lacking; the level of certainty is low. Expert opinion guides this recommendation |
| Expert Opinion Against** | Evidence is lacking; the level of certainty is low. Expert opinion suggests not implementing this intervention |
| Against | Evidence suggests not implementing this intervention or discontinuing ineffective procedures |

*Adapted from the United States Preventive Services Task Force (USPSTF) system

**The USPSTF system defines this category as insufficient evidence and makes I-Statements. They do not make recommendations when the level of certainty in the evidence is low.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Dental caries

Guideline Category

Prevention

Clinical Specialty

Dentistry

Preventive Medicine

Intended Users

Dentists

Guideline Objective(s)

- To update the evidence and address additional questions related to the use of prescription-strength, home-use topical fluorides
- To assist practitioners with decision-making about the use of topical fluoride caries preventive agents

Target Population

Children and adults at risk of developing dental caries

Interventions and Practices Considered

Professional application or prescription-strength home use of topical fluorides (sodium, stannous, and acidulated phosphate fluoride), including varnishes, gels, foams, rinses and prophylaxis pastes

Major Outcomes Considered

Incidence and progression of dental caries

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Description of Methods Used to Collect/Select the Evidence

Literature Search

Two authors used the strategy as presented in Appendix 2 in the original guideline document to search MEDLINE through PubMed and the Cochrane Library. In addition, two authors hand-searched references of relevant recent systematic reviews and other selected articles in order to include studies that might have been missed through the electronic sources.

Figure 1 in the original guideline document shows the process and results of the literature screening process. MEDLINE (through PubMed) was searched from 1965 through March 4, 2011 resulting in 5,009 articles. An additional search of MEDLINE (through PubMed) to identify articles on prescription-strength toothpaste was conducted on October 5, 2011 for articles published since 1965 inclusive, which identified 23 articles. A second electronic database (The Cochrane Library) was also searched from 1965 through March 4, 2011 resulting 1,281 articles. The electronic database searches were all updated on August 30, 2012 resulting in 260 unique hits, for a total of 6,547 articles found. Through a hand-searching process, another 47 articles were identified for consideration.

Two authors independently screened the titles and abstracts using the inclusion and exclusion criteria as shown below and selected 402 articles for full-text review. One author reviewed the manuscripts in full and identified articles for exclusion as reported in Appendix 3 of the original guideline document. Two members of the expert panel reviewed the reasons for exclusion and approved the final exclusion list. When a reviewer was uncertain, she referred the papers to the expert panel members for decision. Discrepancies between reviewers were resolved by a third expert panel member and Chair of this workgroup.

Inclusion Criteria

- Prospective human controlled clinical studies (randomized or non-randomized)
- Fluoride agents requiring professional application or prescription
- Studies that report caries incidence, arrest or reversal as outcomes

Exclusion Criteria

- Studies irrelevant to the topic
- *In vitro* and animal studies
- *In situ* studies using material surrogates (e.g., studies with removable appliances hosting enamel slabs)
- Studies where the only reported outcome was increased salivary flow or reduction in *Streptococcus mutans*
- Split-mouth designs
- Cross-over design
- Studies in which the experimental arm had other co-interventions (fluorides/oral hygiene [OH] instruction etc.) in which the control arm did not. (e.g., Exp: chlorhexidine [CHX] + fluoride [F]; Control: F)
- Studies that have sealants or toothpaste as the control group, except for studies that evaluated home use products
- Studies reporting on fluoride-releasing dental materials
- Studies reporting on slow release devices
- Baseline caries data not reported
- Abstracts only
- Non English
- Post-treatment results and effect of cessation of intervention
- Products that are commercially available as over-the-counter (OTC)
- APF (acidulated phosphate fluoride) Varnish
- Studies that do not report the concentration of fluoride
- Short-term (less than 1 year) studies unless the study reported frank cavitation in less than a year
- Studies on products that are not commercially available in the U.S.

Number of Source Documents

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Level of Certainty Categories for Summary Effect Estimates*

| Level of Certainty in Effect Estimate | Description |
|---------------------------------------|--|
| High | <p>The body of evidence usually includes consistent results from well-designed, well-conducted studies in representative populations. This conclusion is unlikely to be strongly affected by the results of future studies.</p> <p>This statement is strongly established by the best available evidence.</p> |
| Moderate | <p>As more information becomes available, the magnitude or direction of the observed effect could change, and this change could be large enough to alter the conclusion.</p> <p>This statement is based on preliminary determination from the current best available evidence, but confidence in the estimate is constrained by one or more factors, such as:</p> <ul style="list-style-type: none">• The number, size, or risk of bias of individual studies• Inconsistency** of findings across individual studies• Limited applicability due to the populations of interest• Lack of coherence in the chain of evidence |
| Low | <p>More information could allow a reliable estimation of effects on health outcomes.</p> <p>The available evidence is insufficient to support the statement or the statement is based on extrapolation from the best available evidence. Evidence is insufficient or the reliability of estimated effects is limited by factors such as:</p> <ul style="list-style-type: none">• The limited number or size of studies• Important flaws in study design or methods leading to high risk of bias• Inconsistency** of findings across individual studies• Gaps in the chain of evidence• Findings not applicable to the populations of interest• A lack of information on important health outcomes |

*Adapted from the United States Preventive Services Task Force (USPSTF) system

**Inconsistency of findings is a concept incorporating direction of effect, similarity of point estimates, overlapping of confidence intervals, and statistical heterogeneity. Statistical heterogeneity (I^2) is interpreted as: $I^2 < 50\%$ is low; $50 < I^2 < 75\%$ is moderate; $I^2 > 75\%$ is high. Direction of effect and overlapping confidence intervals are also taken into account.

Methods Used to Analyze the Evidence

Meta-Analysis

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Critical Appraisal of Included Studies

The grading system used in the original guideline document was adapted from the United States Preventive Service Task Force (USPSTF) system. The guideline panel assessed the following four key elements in their critical appraisal process: Randomization, allocation concealment, blinding and losses to follow-up. All panel members participated in an orientation through a conference call to standardize the application of the critical appraisal criteria. Each panel member received five to seven studies to review, along with a standardized data abstraction form. Independent from the panel members, one of three authors duplicated the review and critical appraisal of all included studies independently and blinded to the panel's review. This ensured appraisal by two independent and blinded reviewers and standardized application of the criteria by all reviewers. During a three-day face-to-face panel meeting, all panel members reviewed and extensively discussed results from each study.

Each included trial was critically appraised according to the criteria displayed in Table 3 of the original guideline document, which are formatted such that a "yes" response indicates low risk of bias. The number of "yes" answers was counted to provide a risk of bias score. The numerical values of the risk of bias score generally can be interpreted as: 9-11 = low risk of bias; 7-8 = moderate risk of bias; and 0-6 = high risk of bias. Note that studies were assessed based on the methods they reported, sometimes without certain knowledge of the methods actually used.

Data Synthesis and Meta-Analysis

Choice of Outcome Measures

Caries increment was the primary outcome measure, which is the number of newly decayed, missing and/or filled surfaces or teeth experienced by each participant per year compared to baseline. Caries increment is derived from longitudinal and not cross-sectional studies. The panel adapted a set of rules published in a Cochrane review of caries trials to select outcome data from each study for subsequent analysis. Specifically, the panel chose data for "all surface types combined" over data for "specific types (surfaces)" only; data for "all erupted and erupting teeth combined" over data for "erupted" only, and this over data for "erupting only"; data from "clinical and radiological examinations combined" over data from "clinical" only, and this over "radiological" only; decayed, missing or filled surfaces or teeth surfaces (DMFS) scores over decayed, filled surfaces (DFS) or decayed surfaces (DS); net caries increment data over crude (observed) increment data; and follow-up nearest to three years (often the one at the end of the treatment period) over all other lengths of follow-up.

When data on both the tooth surface-level and tooth-level were available, the panel extracted data for both. Similarly, the panel extracted data for "dentinal/cavitated" caries lesions, as well as for "all stages" (these data are presented in Appendix 3 in the original guideline document). The panel also extracted data for primary and permanent teeth separately.

Imputing Variances

When needed and possible, the panel imputed non-reported standard deviations using a linear regression equation.

Adjusting for Cluster-Randomization

Some studies used group randomization (groups such as schools or classes as opposed to individuals receiving the same intervention). In some of these studies, the results were not adequately adjusted for the unit of analysis being the cluster rather than the individual. Standard statistical procedures for adjustment for clustering depend on the number of clusters and the intraclass correlation coefficient (ICC). The ICC ranges from 0 to 1, with the smaller number indicating the smaller cluster effect and vice versa; however, it is often not reported, thus requiring estimation. The standardized mean difference (SMD) for three ICC values (0, 0.1, and 0.2) were calculated, and the resulting effects on the SMD are presented, when applicable.

Effect Estimates

Individual study results were combined by meta-analysis when multiple papers using comparable methods were included for the same fluoride agent, with the objective of obtaining a more powerful estimate of the true effect size. The SMD between the treatment and control arms was used as the effect estimate, since it indicates whether the intervention is effective (i.e., works or does not work) and allows measures on a variety of scales to be combined.

Data on cavitated surfaces were used in the meta-analysis calculations when both surface- and tooth-level cavitated data were extracted. When only all stages data were reported, those data were also included in the meta-analysis with cavitated data. When only tooth-level cavitated data were reported, the data were summarized separately.

For individual studies judged to be too clinically heterogeneous to combine into a meta-analysis, SMD between the treatment and control arms in each study was used as the summary estimate. Individual study results (as SMD), if present, are shown in a table along with the meta-analysis

results, and not presented graphically in a forest plot. All analyses were designed to assess superiority, not equivalence.

Clinical Interpretation Issues

Other systematic reviews on topical fluorides presented prevented fraction (PF), number needed to treat (NNT), and SMD as their effect estimates. The panel chose a pragmatic approach to summarize and interpret the data, which was to summarize one effect estimate (SMD), and then provide conversions of that estimate into both PF and NNT for those more familiar with these effect estimates. The methods are described in Appendix 5 in the original guideline document, and the results are presented in each topical fluoride section. The methods originate from the observation that the character of DMFS data (that mean caries increments are similar to their standard deviations) implies that meta-analysis of SMD (the difference between two means divided by an estimate of the within-group standard deviation) is similar in magnitude to PF (the difference in mean caries increments between the treatment and control groups divided by the mean increment of the control group). The panel notes that the regression equation used to convert SMD to PF in Appendix 5 in the original guideline document was derived from studies on topical fluorides reviewed in this report and is not generalizable beyond this report. In addition, the NNT in this report was based on an annual caries increment of 1 DMFS in the control group.

Generating Forest Plots

Random-effects meta-analyses were conducted throughout to generate forest plots using Review Manager (RevMan) 5.1 software when there were two or more combinable trials. The random effects method (rather than the fixed effect method) is recommended when trial data are taken from the literature and likely do not represent the same population. The random effects model is more conservative in that the variance is composed of both the within-study and between-studies sampling errors. Individual study and summary effect estimates were weighted by the inverse of the variance according to standard methods.

Statistical Heterogeneity

Heterogeneity in study results typically arises from differences in study methodology and/or differences in the clinical aspects of the trial, such as populations, time period of the study, and/or topical fluoride dose. The panel assessed heterogeneity from the forest plots based on the I^2 statistic generated by Review Manager software. The statistical heterogeneity was interpreted as: $I^2 < 50\%$ is low; $50 < I^2 < 75\%$ is moderate; and $I^2 > 75\%$ is high.

Methods Used to Formulate the Recommendations

Expert Consensus (Consensus Development Conference)

Description of Methods Used to Formulate the Recommendations

The authors are a multidisciplinary panel of experts convened by the American Dental Association (ADA) Council on Scientific Affairs (CSA) to present evidence-based clinical recommendations on professionally-applied and prescription-strength, home-use topical fluoride agents for caries prevention.

The authors addressed three clinical questions:

1. In primary and permanent teeth, does the use of a topical fluoride compared to no topical fluoride reduce the incidence of new lesions, or arrest[^] or reverse[^] existing coronal and/or root caries?
2. For primary and permanent teeth, is one topical fluoride agent more effective than another in reducing the incidence of, or arresting[^] or reversing[^] coronal and/or root caries?
3. Does the use of prophylaxis before application of topical fluoride reduce the incidence of caries to a greater extent than topical fluoride application without prophylaxis?

[^]Although the original clinical questions asked about arresting and reversing coronal and/or root caries, insufficient data were found to answer the question; therefore, these outcomes are not addressed in the clinical recommendations (see the "Major Recommendations" field).

Process for Developing Evidence Statements

The first step in this process was to systematically compare the 95% confidence interval of the summary effect estimate to the null for each intervention. If the 95% confidence interval of the summary effect estimate included the line of no effect (zero for difference measures such as standardized mean difference [SMD]), the topical fluoride was judged not to have an effect. If the 95% confidence interval of the summary effect

estimate did not include the line of no effect, the topical fluoride was judged to have a statistically significant effect.

The next step in the development of evidence statements was to classify the level of certainty in the summary effect estimate as high, moderate, or low, according to a standardized grading system (see the "Rating Scheme for the Strength of the Evidence" field). The level of certainty refers to the probability that the panel's assessment of the effect of an intervention is correct. The criteria for assessment include the risk of bias of the included studies, number of studies, number of participants, and statistical heterogeneity among the studies; the consistency in the magnitude and direction of the effect; and the generalizability of the findings to the populations of interest. The possibility of publication bias was not assessed, since there were not enough studies in any category to make a reliable judgment.

Finally, the panel used a consensus method to generate statements that summarized the evidence, including whether or not the intervention was shown to be beneficial, the level of certainty in the underlying evidence, and other clinical information with respect to the population, dentition type, and frequency of application for each topical fluoride agent that was reviewed. The evidence statements were approved by majority vote.

Deviations from the Protocol

Although the panel was interested in the effect of topical fluoride agents on the arrest and reversal of caries progression as stated in clinical question #1, insufficient evidence was found on these outcomes. Therefore, the panel decided to focus the clinical recommendations only on the reduction of caries increment as a measure of caries prevention.

Regarding clinical question #2, the panel was interested in the comparative effectiveness of different topical fluoride agents. Because insufficient evidence was found on which to base clinical recommendations, the panel was unable to address this question.

Methods for Developing Clinical Recommendations

The panel developed clinical recommendations and graded the strength of the recommendations according to a standardized process. The expert panel ascertained the *net benefit rating* by judging the balance of benefits to the potential for harms. For example, if a topical fluoride was found to be effective, and the benefits were judged to outweigh the harms, the net benefit was "benefit outweighs harms." The panel used the criteria displayed in Table 5 of the original guideline document to combine the *Level of Certainty* with the *Net Benefit Rating* to arrive at the strength of the recommendation (*Strong, In Favor, Weak, Expert Opinion For, Expert Opinion Against, or Against*). See the "Rating Scheme for the Strength of the Recommendations" field for definitions.

Note that as described in Table 4 in the original guideline document, for Low level of certainty (when evidence is insufficient or reliability of estimated effects is limited) and Table 5 in the original guideline document, the expert panel can still make a recommendation based on their collective judgment, based on the available evidence. Upon agreement that the level of certainty in the effect was low, and when the panel decided to make a clinical recommendation, the language of that recommendation was discussed and amended until a majority of the panel was satisfied, as assessed by vote.

Rating Scheme for the Strength of the Recommendations

Definitions for the Strength of Recommendations*

| Grade | Strength of Recommendation |
|--------------------------|--|
| Strong | Evidence strongly supports providing this intervention |
| In Favor | Evidence favors providing this intervention |
| Weak | Evidence suggests implementing this intervention after alternatives have been considered |
| Expert Opinion For** | Evidence is lacking; the level of certainty is low. Expert opinion guides this recommendation |
| Expert Opinion Against** | Evidence is lacking; the level of certainty is low. Expert opinion suggests not implementing this intervention |
| Against | Evidence suggests not implementing this intervention or discontinuing ineffective procedures |

*Adapted from the United States Preventive Services Task Force (USPSTF) system.

**The USPSTF system defines this category as insufficient evidence and makes I-Statements. They do not make recommendations when the level of certainty in the evidence is low.

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

The panel approved clinical recommendations by a simple majority vote. The panel sought comments on this report from other subject matter experts, methodologists, epidemiologists and end-users before finalizing the recommendations. The American Dental Association (ADA) Council on Scientific Affairs (CSA) approved the final report for publication.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field). All included evidence is from either randomized controlled trials or controlled clinical trials.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Appropriate use of professionally-applied and home-use topical fluoride for prevention of dental caries

Potential Harms

Potential harms of topical fluorides include, but may not be limited to, the following:

- Nausea and vomiting associated with the ingestion of topical fluorides.
- Dental fluorosis (an esthetic concern) while tooth enamel is developing until about age 6, due to daily ingestion of topical fluoride, such as from toothpaste or from prescription home use gels. There is less of a concern with professionally-applied topical fluorides that have much longer intervals between applications. Additionally, fluoride varnish has less potential for harms than other forms of high concentration topical fluoride because the amount of fluoride that is placed in the mouth with fluoride varnish is approximately one-tenth that of other professionally-applied products.

The panel judged that the benefits outweighed the potential for harms for all professionally-applied or prescription-strength topical fluorides and age groups except for children under age 6, where the risk of swallowing and associated events (particularly nausea and vomiting) outweighed the potential benefits for all professionally-applied or prescription-strength topical fluorides except 2.26% fluoride varnish.

Qualifying Statements

Qualifying Statements

- This report is intended to assist practitioners with decision-making about the use of topical fluoride caries preventive agents. The panel notes that lack of clinical data, changes in formulations across time, and a wide variety of products can hamper decision-making.
- The recommendations in this document do not purport to define a standard of care, but rather should be integrated with each practitioner's professional judgment and each patient's needs and preferences.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Patient Resources

Quick Reference Guides/Physician Guides

Resources

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Staying Healthy

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

Weyant RJ, Tracy SL, Anselmo T, Beltr n-Aguilar ED, Donly KJ, Frese WA, Hujoel PP, Iafolla TJ, Kohn W, Kumar J, Levy SM, Tinanoff N, Wright JT, Zero D, Aravamudhan K, Frantsve-Hawley J, Meyer DM. Topical fluoride for caries prevention. Chicago (IL): American Dental Association; 2013 Nov. 118 p. [118 references]

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2006 Aug (revised 2013 Nov)

Guideline Developer(s)

American Dental Association - Professional Association

Source(s) of Funding

The American Dental Association (ADA) Council on Scientific Affairs commissioned this work and the Centers for Disease Control and Prevention (CDC) partly funded this project.

Guideline Committee

American Dental Association (ADA) Council on Scientific Affairs Expert Panel on Professionally Applied or Prescribed Topical Fluoride

Composition of Group That Authored the Guideline

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Financial Disclosures/Conflicts of Interest

Robert J. Weyant, DMD, DrPH did not report any conflicts. Theresa (Tracy) Anselmo, MPH, BSDH, RDH served on the Council on Public Health for the American Dental Hygienists' Association ending in June 2012. Eugenio D. Beltrán-Aguilar, DMD, MPH, MS, DrPH is the Director of the American Board of Dental Public Health. Kevin J. Donly, DDS, MS is a Pediatric Dentistry Commissioner to the American Dental Association (ADA) Commission on Dental Accreditation. William A. Frese, MD is the American Academy of Pediatrics Section VII Oral Health liaison and also an advocate of oral health for the Illinois Oral Health Chapter of the American Academy of Pediatrics. Philippe P. Hujoel, MSD, PhD is a Consultant to Delta Dental. Timothy Iafolla, DMD, MPH did not report any disclosures. William Kohn, DDS holds material financial interest in a business that furnishes or is seeking to furnish goods or services to the ADA and publically represents Delta Dental Plans Association at various meetings and events. Jayanth Kumar, DDS, MDH is the ASTDD Perinatal Committee Chair (2010 to present). Steven M. Levy, DDS, MPH was the President of the American Board of Dental Public Health during the development of this report. Norman Tinanoff, DDS, MS is on the Board of Trustees of the Dentaquest Foundation, an organization with a mission to improve access to oral health care, and receives no compensation and occasionally does advocacy work for the University of Maryland Dental Action Coalition regarding oral health issues. J. Timothy Wright, DDS, MS serves as a consultant to Edimer, which is a company working on ectodermal dysplasia protein therapy. Domenick Zero, DDS, MS serves on the Johnson & Johnson Oral Care Advisory Board, receives compensation from Unilever for moderating a symposium at the 2011 IADR Annual Meeting and consults on an ad hoc basis for GSK, Colgate, and P&G. Krishna Aravamudhan, BDS, MS; Sharon L. Tracy, PhD; Julie Frantsve-Hawley RDH, PhD; Daniel M. Meyer, DDS have no disclosures.

Guideline Status

This is the current release of the guideline.

This guideline updates a previously released version: American Dental Association Council on Scientific Affairs. Professionally applied topical fluoride: evidence-based clinical recommendations. J Am Dent Assoc. 2006 Aug;137(8):1151-9. [45 references]

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

Electronic copies: Available in Portable Document Format (PDF) from the [American Dental Association Web site](#) .

Print copies: Available from the American Dental Association Council on Scientific Affairs, 211 E. Chicago Ave., Chicago, Ill. 60611.

Availability of Companion Documents

The following are available:

- American Dental Association Council on Scientific Affairs. Topical fluoride for caries prevention: executive summary of evidence-based clinical recommendations. Chicago (IL): American Dental Association; 2013 Nov. 14 p. Electronic copies: Available in Portable Document Format (PDF) from the [American Dental Association \(ADA\) Center for Evidence-Based Dentistry \(EBD\) Web site](#) .
- Professionally applied topical fluoride: evidence-based clinical recommendations. Chairsides guide. Chicago (IL): American Dental Association; 2013. 2 p. Electronic copies: Available in PDF from the [ADA Center for EBD Web site](#) .
- American Dental Association Council on Scientific Affairs. Topical fluoride for caries prevention: podcast with Dr. Robert Weyant. Chicago (IL): American Dental Association; 2013 Nov. Available in audio format from the [ADA Center for EBD Web site](#) .

Patient Resources

The following is available:

- Fluoride and fluoridation. Resource website for information on fluoride. 2013. Electronic copies: Available from the [American Dental Association Web site](#) .

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